

Oxford Vaccine Group

Centre for Clinical Vaccinology and Tropical
Medicine

Churchill Hospital
Headington, Oxford

OX3 7LE

Tel: 01865 611400

Email: resceu@ovg.ox.ac.uk

Website: snottynose.org



Understanding RSV: Severe disease and the long term consequences

Study Information Booklet

You are invited to take part in a study to help us learn more about the virus that most commonly causes coughs, colds and chest infections in young children, and sometimes causes children to be so unwell they have to be admitted to hospital.

The study is being run by the Oxford Vaccine Group (OVG) which is part of the University of Oxford.

Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information please contact the study team (details above).

Thank you for taking the time to consider taking part in the study.

Who are the Oxford Vaccine Group?

The Oxford Vaccine Group is part of the University of Oxford and is an independent research team of doctors, nurses and play assistants. We carry out research studies on infectious diseases and vaccines for babies, young children, teenagers and adults and teach doctors and nurses about immunisations. In the past 5 years alone, over 7000 participants in the Thames Valley area have taken part in our research studies.

Why have I been approached about the study?

You have been approached about the study because your child is under 12 months, is healthy and you are living in the UK, in an area that is taking part in the study. Just over 300 children will be enrolled into this study in the UK. Around 40 children will be healthy with no respiratory illness.

What is Respiratory Syncytial Virus (RSV) and why is it important?

RSV is the most common viral cause of coughs, colds and chest infections in infants. More than half of children will be infected in the first year of life, mostly during the winter. Most infections are mild (runny nose, cough and cold), but in some cases infants develop a severe chest infection requiring admission to hospital. In the winter months, RSV is responsible for around 1 in 6 of all hospital admissions in infants in the UK. Worldwide, RSV is the second largest cause of death in children under one year of age after malaria, mostly in Africa and Asia. In addition, about half of children who develop an RSV chest infection go on to have symptoms of asthma, including wheezing and coughing, for the next few years. Currently, there is no treatment to cure or vaccine for prevention of RSV.

What is the purpose of the study?

The purpose of this study is to answer the following questions:

- Why are some children more likely to suffer from severe RSV disease?
- Can we identify which children will suffer from long term problems such as wheezing?
- Are there any measurable signs to indicate who will be protected from having severe disease?

To help us answer all these questions we would look for indicators, called biomarkers in samples of nasal mucous, blood, other body fluids and in the DNA. The DNA contains the genetic instructions that are transferred from parents to their children which determine the child's characteristics, such as how tall they are or the colour of their eyes.

We will also enrol healthy children, that haven't had a respiratory illness for 14 days. These children will act as 'controls', so that we can compare any indicators found in children with RSV to those in children without an infection.

Will my child be eligible for this study?

Your child can participate in this study if he or she is;

- aged less than 12 months
- does not have any significant medical illness
- was born at more than 37 weeks gestation
- has not had a respiratory illness in the last 7 days
- has not received vaccines in the last 7 days

Does my child need to take part in this study?

Taking part in this study is completely voluntary and if you decide to say no, it will not affect your child's routine care in any way. You are also free to change your mind and withdraw your child at any time without giving an explanation.

What happens in the study?

If you decide you would like to take part in this study, a member of the research team either from the hospital you are attending or from the Oxford Vaccine Group (OVG) would talk you through the study and answer any questions you may have before asking you to sign a consent form. Visits will either happen in the hospital or at your home.

Medical history

We would ask you some questions about your child's health and may need to take some information from their medical records, either through their GP or through the hospital system so as to confirm their eligibility for the study.

Collection of samples

We would collect **samples of** nasal mucous, blood, urine and stool sample on one occasion. Details on their collection are further below.

Follow up

We would contact you one week after the samples above were collected to assess if your child developed any illness since we last saw you.

Yearly Questionnaires

We would follow up your child every year by asking you to complete online questionnaires about your child, yourself and your family's health and living arrangements. The questionnaires shouldn't take any longer than 10 minutes to complete. The study will run for 3 years and if you decide to take part, we will be able to tell you how many years you and your child would be followed up for, although it would be for a maximum of 3 years.

How are the samples collected?

Blood samples

The amount of blood we take would depend on the age and weight of your child but would be less than 5ml (a teaspoon). For the blood tests, anaesthetic cream is used to numb the skin. There will also be a second person to help distract the child. If it is not possible to get the full amount of blood after one attempt, we would ask your permission to have a second attempt.

Nasal sample

Two samples of nasal mucous would be collected. **One** using a swab, which looks like a cotton bud. The swab is passed to the back of the nose as shown below; this can be a bit tickly and uncomfortable but will only take a few seconds and is not painful. **Another swab is used which involves placing a material similar to blotting paper, just inside the nostril.**

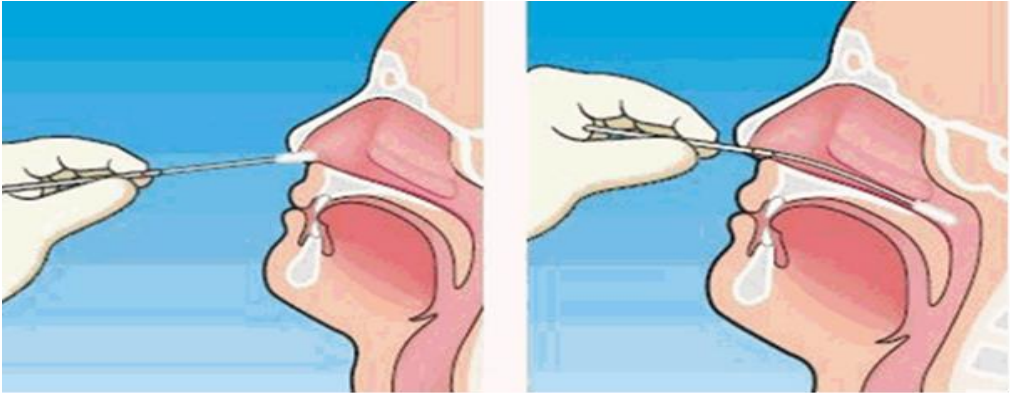


Image taken from: www.thenurseszone.com

Urine and stool samples

These can be collected from your child's nappy. It is possible that a member of the research team will not be present when there is a sample to collect, so we would give you instructions and some gauze or cotton wool to collect them yourself.

We would then provide you with a bag and ask you to store them in your freezer and fridge at home until they can be collected.

What are the possible risks and discomforts of taking part in this study?

There are few risks of participating in this study. Blood and respiratory sampling can be associated with minor local effects, for example, discomfort, bruising or nose bleeds. There are no risks associated with collection of urine or stool samples.

What are the benefits of taking part in this study?

By taking part in the study your child will not have a direct benefit, nonetheless, other children may benefit in the future from what is learned in this study.

What will happen to my child's samples?

The samples we take for this study will be labelled with a study number, not your child's name. Samples will be transferred to and stored in the laboratory at OVG, until they are tested anonymously in certified laboratories, in EU and non EU countries. .

It will not be possible to provide you with any individual results from any of the tests performed (including the tests performed on the genetic material collected) as part of this study. If you choose to take part in this study, we will be asking for your separate permission to store samples taken in a collection called a Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study. You are free to say no to the biobanking of samples but continue to take part in this study. If you do not want your child's samples to be stored in the Biobank, they will be disposed of at the end of the study.

Would my child's taking part in this study be kept confidential?

Any research study records with your child's name and address would be held confidentially by the research staff either in the hospital you were seen in or by the Oxford Vaccine Group. If your child was enrolled in a hospital setting, the research study records (which are different from NHS medical records) will be transferred confidentially to the OVG research team, who will continue the care of your child in this study.

All the information about your child that is collected for the study will be coded with a study number and kept strictly confidential. Only authorised study staff can access your child's data. No data that identifies you or your child will leave the research sites (local hospital or OVG).

Following completion of the study, all study records (which includes some personal data such as name, date of birth and contact details) will be retained up to 3 years after the youngest participant reaches 18 years of age. At that point files will be confidentially destroyed if storage is no longer required under the regulations and guidance applicable at that future point in time.

We would also seek your permission to contact you to invite you to participate in future related research.

By signing the consent form for this study, you would be giving permission for the research staff in your local hospital and OVG, representatives of the Sponsor (Oxford University) and appropriate regulatory authorities to look at your child's medical records and study records to ensure that the study is being conducted correctly.

We will inform your child's GP, health visitor and practice nurse that s/he is taking part in this study and we will contact them every year before sending the questionnaire to you.

The RESCEU Consortium

This study is part of a wider group of studies all trying to identify indicators of severe RSV infection. In total 630 children will be enrolled in countries across Europe. Experts from Universities, hospitals and laboratories have formed a group called RESCEU (Respiratory Syncytial virus Consortium in Europe) to carry out these studies and test the samples. The coded data and samples collected from your child will be combined and shared with the group of experts to help understand and identify indicators of severe RSV infection. Neither you nor your child will be identifiable from the data shared with the consortium. The coded electronic data will be stored on a secure server held by the University of Oxford.

Who is organising and funding the research?

The study is funded by the Innovative Medicines Initiative (IMI), which is a joint undertaking between the European Union (EU) and the pharmaceutical industry association (EFPIA), and is being sponsored by University of Oxford.

What will happen if I don't want my child to carry on with the study?

You can change your mind and withdraw your child from the study at any time without giving any reason. If you change your mind and withdraw your child from the study we would use the samples and data we have collected up until the point you informed us that you wanted to withdraw, unless you inform us in writing that you wish for your child's data and samples to be destroyed.

What will happen at the end of the research study?

You will receive a summary of the study results when the study ends. To allow for full analysis of all participants' data, this information will be released about one to two years after the last child completes their participation in the study. It will not be possible to provide you with any individual results from tests performed as part of this study.

All publications will appear on the OVG website and you will receive a letter summarising these results. Your child would not be identified in any report or publication and we will not provide individual results.

If you are interested in hearing about other research studies that we may be running in the future then there is an option to sign up to a contact list through which we can get in touch. This does not oblige you in any way to take part in the future research.

What if I wish to complain?

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you should contact the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or email the Head of CTRG Heather House ctrig@admin.ox.ac.uk.

What if something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of participating in this study.

What else do I need to know?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by South Central Hampshire A Research Ethics Committee.

So in summary:

- We hope to understand why some children will have severe RSV disease, identify a measure that indicates who is likely to get severe RSV disease and which children will go on to develop long term problems, such as wheezing
- Your healthy child will act as a control. We will take samples from your child once

- We will contact you by phone, email or online to ask questions about your child's health and you and your family's health

What do I do now?

You do not need to make a final decision straight away. Please contact us by:

- e-mail: resceu@ovg.ox.ac.uk
- Telephone: **01865 611400**
- Website: snottynose.org

Members of the research team will be happy to discuss the study with you and answer any questions you may have.

Thank you for considering taking part in this study.

Yours sincerely,



Professor Andrew Pollard
Study Chief Investigator
Professor of Paediatric Infection
and Immunity
Honorary Consultant
Paediatrician